



JAN 30 2004

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Shon Thantrey
General Manager
Makevale Limited
Valley House, Marsh Lane
Ware Herts SG12 9QP
United Kingdom

Dear Mr. Thantrey:

During an inspection of your establishment located in Ware, Hertfordshire, England, on September 1 – 3, 2003, our Investigator determined that your firm manufactures denture, relining, repairing, and rebasing resin (dental polymers and accessories). The dental polymers and accessories are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection also revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a) (1). For example, the corrective and preventive action procedures are inadequate in that: (a)

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the corrective action procedure, 4.14, "Corrective Action," lists only consumer complaints and recalls as data sources for corrective actions, and does not include other available data sources, such as nonconformance, reworked product and returned product; and (b) the preventive action procedure listed under section 8.5.3 of the firm's quality manual, encourages employees to report "near miss" events, but these events are verbally reported with no documentation format or instructions.

2. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR Part 820, as required by 21 CFR 820.20(c). For example, procedure 4.1.3, "Management Review," does not include management with executive responsibility as a participant or directions to review and determine the suitability and effectiveness of the conducted management reviews.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information as required by or under section 519 respecting the devices and 21 CFR Part 803 Medical Device Reporting (MDR) regulation. Your firm failed to develop, maintain, and implement written MDR procedures as required by 21 CFR 803.17. Specifically, your firm does not have specific procedures for reporting adverse events to FDA, including the identification of adverse events received, the directions for reporting events within required time frames, and the method by which the events are reported.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in action without further notice, which may include detaining your products without physical examination upon entry into the U.S. until corrections are completed. (Section 801(a) of the Act, 21 U.S.C. 381(a)). Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Your firm is not required to conduct trend analysis as cited in Observation 1(b) of the FDA 483. However the corrective and preventive action procedures should include an appropriate statistical methodology to detect recurring quality problems.

Since your firm has not had any design projects or changes to any current products since January 1977, design control requirements are exempt. However, design control change procedures are a requirement for your firm, as required by 21 CFR 820.30(i). Section 4.4.9 of the Design Control in the Quality Manual is inadequate and a more detailed protocol should be submitted for FDA's review.

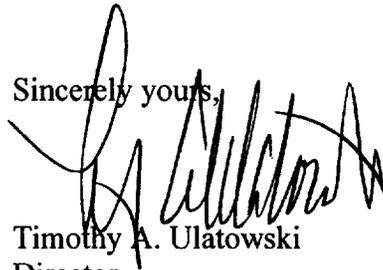
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Please notify this office in writing, within fifteen (15) working days from the date you receive this letter. If documentation is not in English, please provide the English translation to facilitate our review of the specific steps you have taken to correct the noted deviations, including an explanation of how you plan to prevent the recurrence of similar deviations.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A , Dental, Ear, Nose, Throat, & Ophthalmic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Valerie A. Flournoy, CSO or Ronald L. Swann, Branch Chief.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Valerie A. Flournoy at the letterhead address above or via telephone at (301) 594-4613 or via FAX at (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is fluid and cursive, with a large initial "T" and "U".

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health